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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/500,135 | 02/08/2000 | David A. Estell | A-68893/DJB/DAV | 2164 |

7590 06/28/2002

Flehr Hohbach Test Albritton & Herbert LLP
Four Embarcadero Center Suite 3400
San Francisco, CA 94111-4187

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| EXAMINER |
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SAUNDERS, DAVID A

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| ART UNIT | PAPER NUMBER |
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1644

DATE MAILED: 06/28/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.



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16

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/12/02
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2, 5, 7-10, 14, 29-41 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 2, 5, 7-10, 14, 35-38, 40-41 is/are rejected.
- ☒ Claim(s) 29-34, 39 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 14
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON-

Art Unit: 1614

The amendment of 3/12/02 (paper 15) has been entered. Claims 2, 5, 7-10, 14 are 29-41 are pending and under examination.

The amendment has entered no new matter.

✓ The disclosure is objected to because of the following informalities: The sequence listing and the SEQ ID NOS: recited in the specification are inconsistent. For example, the listing of 6/18/01 shows SEQ ID NO. 6 as of *Bacillus lentus subtilisin*, while specification page 9 refers to SEQ ID NO: 6 as of human subtilisin. Applicant should review the entire listing for consistency with the disclosure and make appropriate corrections.

Appropriate correction is required.

Applicant's amendment has overcome the previously stated 112, first paragraph rejections with respect to the description of a "different immunogenic response" and with respect to the scope of enablement.

➤ Claims 8-10, 35-38 and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's disclosure has not adequately described what are sequences from homologues of proteases of interest that are sequences, which produce a lesser allergenic response.

The rejection has been previously set forth (paper 13) against claims 8-10. Newly presented claims 35-38 and 40 contain like language and are therefore, presently, included in the rejection. Applicant has urged (Paper 15, page 7), that one of

skill would know what are homologues of the recited enzymes. While this may be true one of skill could not readily envision which subgenus of such homologues are less allergenic and which subgenus of such homologues have the same or a higher allergenicity than the polypeptide of interest. While one of skill might know how to conduct T-cell proliferative assays that would identify those which are less allergenic, such would be an indication that the invention is enabled, not that it is described. Note the description and enablement aspects of 35 USC 112, first paragraph are to be considered separately. *Vas – Cath v. Mahurkar* 19 USPQ2d 1111.

The effective date of the claims remains as 2/8/00 because applicant could not have recited the Markush group of enzymes in claims 2, 8 or 41 in application 09/060,853 without entry of new matter. Likewise the '853 application could not support what is recited in the concluding paragraph of claim 8 or the first paragraph of claim 35.

Applicant's amendment has overcome the previously stated prior art rejection over King et al.

Claims 2, 5, 7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Siekstra et al (WO 96/34946 or US, 5,837,517), for reasons of record and as explained below.

Claims 2, 5, 7 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bott et al (EP 0,251,446 or US 5,801,038) for reasons of record and as explained below.

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As previously noted, both Sierkstra et al and Bott et al show a subtilisin having a Y171Q substitution, which the examiner consider to be inherently less allergenic than the subtilisin from which it was claimed.

Applicant's urgings of 3/12/02 are unconvincing because they argue that the invention of the prior art references made their modified subtilisins for purposes other than that of reducing allergenicity; the examiner, however, has reasonably argued that these prior art compositions are inherently less allergenic and hence properly anticipate, irrespective of what may have motivated these inventors to modify their subtilisins.

Atlas Powder Co v. IRECO, INC. 51 USPQ2d 1943.

> Claims 2, 5, 7-9, 14, 35-38 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 24, 27 and 30 of copending Application No. 09/060,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejection is stated for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

> Claims 2, 5, 7-9, 14, 35-38 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 17-27 and 30-32 of copending Application No. 255,501. Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejection is stated for reasons of record.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness type double patenting rejections will be maintained on the record and can be resolved if record have been overcome.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Saunders whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday to Thursday from 8 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Saunders/LR

June 19, 2002

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER

ART UNIT ~~182~~ 1644